K001775

ZOE Medical

510(k) Summary

JAN 12 2001

[as required by section 807.92(c)]

1 Submitter

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Date this Summary was Prepared: June 08, 2000
Date this Summary was Modified: September 22, 2000

2 Trade Name, Common Name, Classifications

2.1 Trade Name

ZOE Nightingale Monitoring System

2.2 Common Name, Classifications

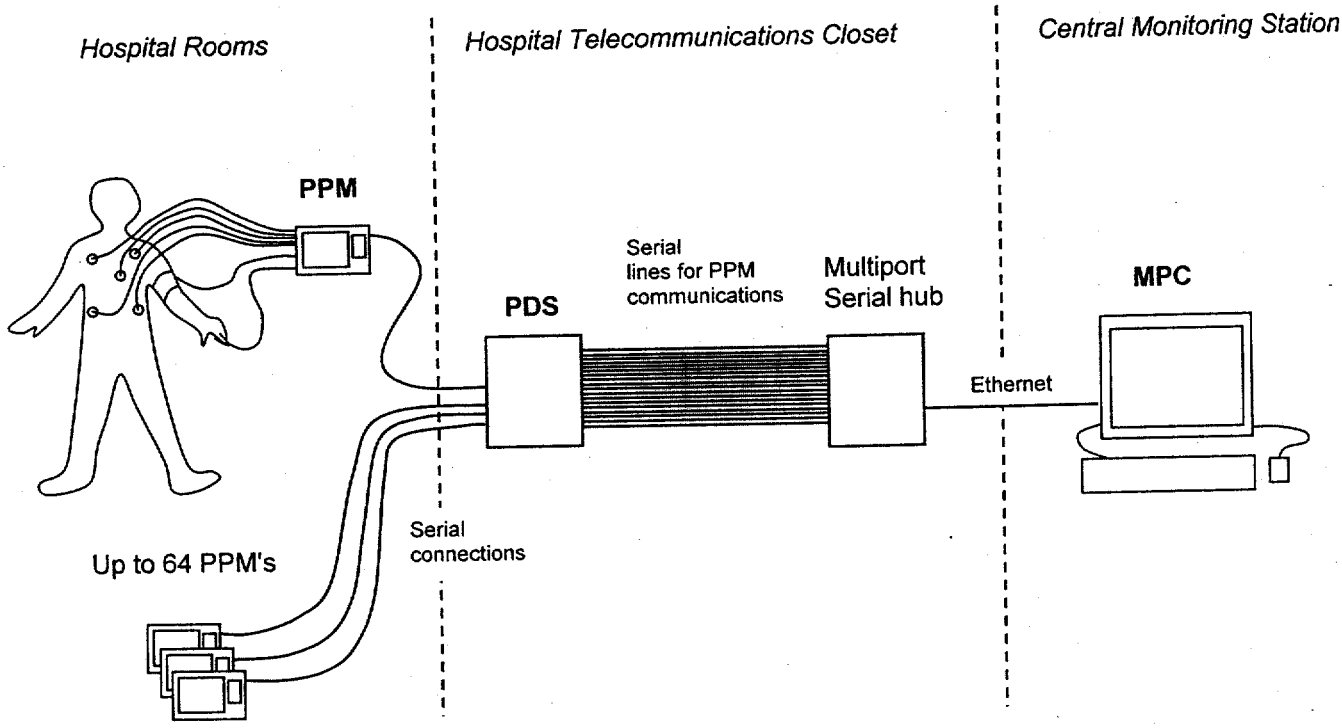
Common Name	Classification Name	Product Code	Class	Regulation Number
Cardiac Monitor	Monitor, Cardiac (including cardiotachometer and rate alarm)	DRT	II	21 CFR 870.2300
Breathing Frequency Monitor	Monitor, Breathing Frequency	BZQ	II	21 CFR 868.2375
Clinical Electronic Thermometer	Thermometer, Electronic, Clinical	FLL	II	21 CFR 880.2910
Oximeter	Oximeter	DQA	II	21 CFR 870.2700
Noninvasive Blood Pressure Measurement System	System, Measurement, Bloodpressure, Non-Invasive	DXN	II	21 CFR 870.1130
Medical Cathode Ray Tube Display	Display, Cathode-Ray Tube, Medical	DXJ	II	21 CFR 870.2450

3 Predicate Device Identification

The legally marketed devices to which we claim substantial equivalence [807.92(a)(3)] are the Siemens SC6000 Monitor and the Siemens SC3000 Multiview Central Display.

4 Device Description and System Diagram

The main components of the Nightingale Monitoring System are shown in the following diagram:



The **PPM** (Personal Patient Monitor) component acts primarily as a data acquisition module for the system.

The **PDS** (Patient Data Switch) connects the PPM serial cables to a commercial serial hub device.

The **MPC** (Multi-Patient Central) provides the central monitoring and alarming functions for the system.

4.1 PPM Description

The PPM is a small, light weight patient monitor that resides with the patient. The PPM performs four basic functions:

1. it acquires physiological signals from the patient,

2. it determines and displays the following parameters:

   Heart Rate (HR)
   Respiration Rate (RR)
   Saturated Percent O_2 (SpO_2)
   Pulse Rate (PR)
   Noninvasive Blood Pressure, Systolic (NBPs)
   Noninvasive Blood Pressure, Mean (NBPm)
   Noninvasive Blood Pressure, Diastolic (NBPd)
   Temperature (TEMP)

3. it displays three waveforms, selectable from the following list:

   ECGI
   ECGII
   ECGIII
   ECGV
   Respiration
   SpO_2

4. it transmits the parameters and waveforms enumerated in (2) and (3) above over a serial line to the central station.

4.2 PDS Description

The PDS provides serial connections between the PPM serial cables and a commercial multi-port serial hub. The serial hub relays the data to and from all the PPM serial connections using a single Ethernet cable to the MPC.

4.3 MPC Description

The MPC is a Windows based workstation that manages up to 64 simultaneous PPM serial data connections. The MPC is responsible for features such as alarm handling, parameter trending, and reporting. Physiological alarms are sounded at the MPC. The PPM does not annunciate physiological alarms, it is primarily a data collection module. The MPC main screen presents a view of 64 small view areas, each displaying data from one connected PPM. The MPC main screen also contains two large view areas for viewing data from selected PPM's. The MPC operator selects a PPM for viewing in one of the large view areas by clicking on the small view area corresponding to that PPM. Figure E-1 shows the relationship between the PPM's and the view areas on the MPC main screen.

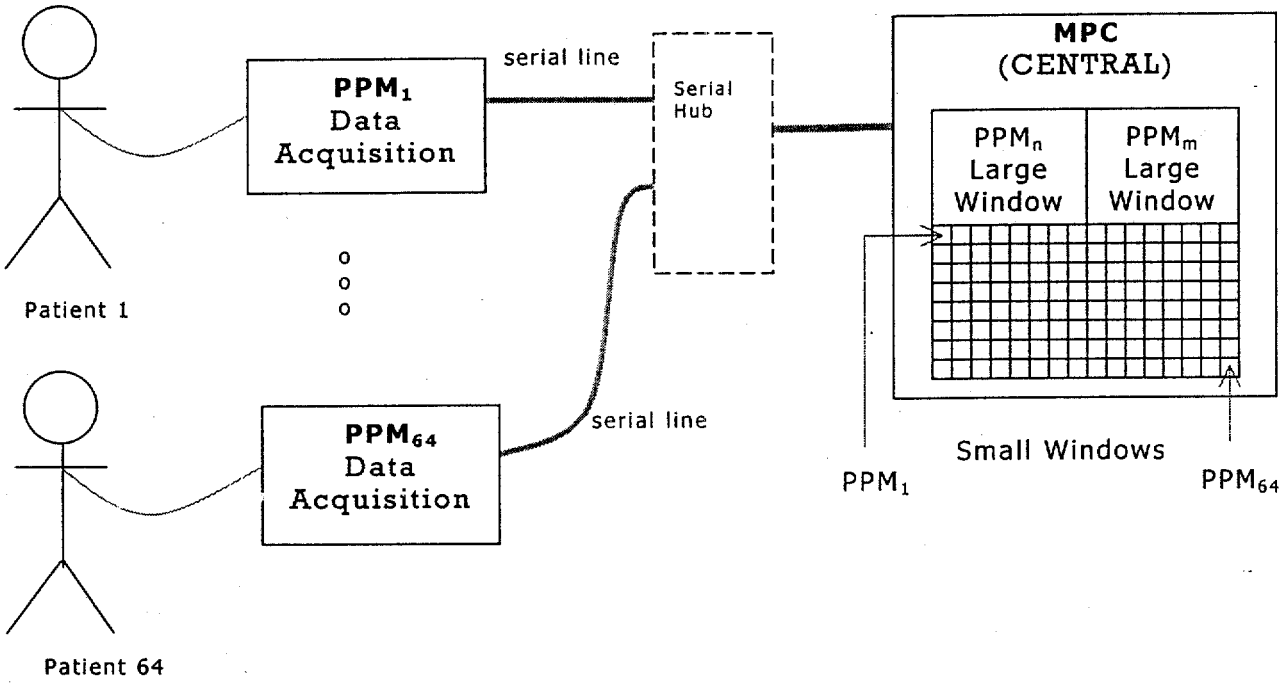


Figure E-4 Mapping of PPMs to MPC small view areas

4.4 MPC Alarms

Alarm handling in the Nightingale Monitoring Systems is centrally managed by the MPC. The individual PPM's calculate and transmit parameter values, but do not alarm (other than in the limited cases specified below). All alarms related to physiological conditions, whether special conditions such as asystole, or limit violations, are managed by the MPC. The MPC uses a combination of color, flashing, icons, and audio tones to convey alarm status information to the user. The MPC operator uses independent functions to silence the alarm tones, and to acknowledge alarms from a specific PPM. All alarm limit settings, alarm enable/disable settings, and other settings that control the alarm behavior of the system are done by the operator at the MPC.

4.5 PPM Alarms

Since the Nightingale Monitoring System manages alarms centrally, the PPM has only a limited alarm function. There are just two cases when the PPM will sound an alarm tone and display an alarm message: (1) if the serial communication link to the MPC is ever lost, once it has been established; and (2) if the internal temperature of the PPM gets too high. The MPC has no remote control over these two alarms. A user at the PPM may silence the PPM alarm tone temporarily in these cases, but the tone will resume after a set time if the condition has not been corrected.

5 Intended Use

The intended use of this device is to collect and display the following signals and parameters:

- ECG
- Heart Rate
- Respiration Rate
- Temperature
- Systolic, Mean, and Diastolic Blood Pressure (non-invasive)
- Functional Oxygen Saturation of Arterial Hemoglobin (SpO_2)
- Pulse Rate

This device is intended to be used to issue audible and visible alarms when any or all of the following parameters exceed preset limits:

- Heart Rate
- Respiration Rate
- Systolic Blood Pressure
- Mean Blood Pressure
- Diastolic Blood Pressure
- Oxygen Saturation Percent
- Pulse Rate

This device is intended to be used by a qualified healthcare professional (e.g. Physician, Nurse, Technician) on an adult patient in a healthcare environment.

6 Technological Characteristics Compared

ZOE Medical Nightingale Monitoring System vs. Predicate Device

New Device = ZOE Medical Nightingale Monitoring System
Predicate Device = Siemens SC6000 / SC3000

Table 1: Technology and Features Comparison: New Device vs. Predicate

Technology / Features Comparison	**Nightingale Monitoring System**	**Siemens SC6000 Patient Monitor with SC3000 Multiview**	**Explanation of Differences: Nightingale as Compared to Predicate**
Manufacturer	ZOE Medical Incorporated	Siemens Medical Systems	

Technology / Features Comparison	Nightingale Monitoring System	Siemens SC6000 Patient Monitor with SC3000 Multiview	Explanation of Differences: Nightingale as Compared to Predicate
Intended Population	Adult	Adult, Pediatric, Neonatal	Subset
Intended Use	The intended use of this new device is to collect and display the following signals and parameters: ECG, Heart Rate, Respiration Rate, Temperature, Systolic, Mean, and Diastolic Blood Pressure (non-invasive), Functional Oxygen Saturation of Arterial Hemoglobin (SpO_2), and Pulse Rate. This new device is intended to be used to issue audible and visible alarms when any or all of the following parameters exceed preset limits: Heart Rate, Respiration Rate, Systolic Blood Pressure, Mean Blood Pressure, Diastolic Blood Pressure, Oxygen Saturation Percent, Pulse Rate. This new device is intended to be used by a qualified healthcare professional (e.g. Physician, Nurse, Technician) on an adult patient in a healthcare environment.	The intended use of this predicate device is to measure heart rate; respiration rate, invasive pressure, non-invasive pressure, adult arrhythmia, temperature, arterial oxygen saturation, pulse rate, central apnea, and adult ST segment analysis. This predicate device will produce visual and audible alarms if any of the above parameters vary beyond preset limits and produce timed or alarm recordings. This predicate device may be connected to the SC3000 Multiview Central Station over Siemens' network.	Subset

Technology / Features Comparison	Nightingale Monitoring System	Siemens SC6000 Patient Monitor with SC3000 Multiview	Explanation of Differences: Nightingale as Compared to Predicate
Indications for Use	The device is indicated for use in adult patient populations in an environment where patient care is provided by healthcare professionals (e.g. Physician, Nurse, Technician) when the professional determines that a device is required to measure any or all of the following patient parameters: Heart Rate Respiration Rate Temperature Systolic, Mean, and Diastolic Blood Pressure Functional Oxygen Saturation of Arterial Hemoglobin (SpO_2) Pulse Rate And, The professional determines that a device is required to issue visible and audible alarms when any or all of the following parameters exceed preset limits: Heart Rate Respiration Rate Temperature Systolic Blood Pressure Mean Blood Pressure Diastolic Blood Pressure Oxygen Saturation Percent Pulse Rate	The predicate device's Indications for Use are not explicitly stated in the K974492 510(k) Summary. When the parameters and alarms described in the new device's Indications for Use are researched in the predicate device's User's Guide, it shows that the Indications for Use for these parameters and alarms is the same.	Subset

Technology / Features Comparison	Nightingale Monitoring System	Siemens SC6000 Patient Monitor with SC3000 Multiview	Explanation of Differences: Nightingale as Compared to Predicate
Number of Electrodes Employed	5 RL, RA, V, LA, LL	3 or 5 5: RL,RA,V,LA,LL	
Bandwidth (-3dB)	0.4Hz to 50Hz	0.5Hz to 40Hz	
Input Dynamic Range	± 20 mV	± 15mV	
Sweep Speed	25 mm/s	25 mm/s	
Display Mode	Eraser Bar	Eraser Bar	
Bedside Display	240 x 320 EL Monochrome	240 x 240 LCD Color	Nightingale bedside Displays more channels
Central Display	21" diagonal monitor	19" diagonal monitor	
Central Processing Unit for Patient Data Acquisition and Bedside Display	AMD 100 MHz SC400	Motorola 68302 Texas Instruments TMS34010	Nightingale acquires less data Nightingale's bedside display is simpler and does not require a special graphics processor
Central Processing Unit for Central Display	Intel 500 MHz Pentium III or better	Power PC	
Operating System for Patient Data Acquisition and Bedside Display	MS-DOS 6.22	VRTX-32	Nightingale bedside is a simple device and does not require a multi-tasking operating system
Operating System for Central Display	Microsoft Windows NT	AIX (UNIX)	
Bedside Display: Number of Waveforms	Three	Two	

Technology / Features Comparison	Nightingale Monitoring System	Siemens SC6000 Patient Monitor with SC3000 Multiview	Explanation of Differences: Nightingale as Compared to Predicate
Central Display: Number of Waveforms	Up to 70: (two large views x 3 waveforms each) + (64 small views x 1 waveform each) = 70	Up to 16: 1 large view or 16 small views	Nightingale Central display has more area, narrower small views than the SC3000 central display
Bedside Physiological Alarms	No	Yes	Nightingale bedside is only a data acquisition module
Bedside Technical Alarms	Yes	Yes	Nightingale bedside will only alarm when communication link to central is interrupted
Remote Silencing of Bedside Alarms	No	Yes	Remote alarm silencing is discouraged by FDA guidance
Central Display Physiological Alarms	Heart Rate Respiration Temperature SpO_2 Pulse Rate NBP Systolic NBP Mean NBP Diastolic	Heart Rate Respiration SpO_2 Pulse Rate NBP Systolic NBP Diastolic	Nightingale has additional alarms on Temperature and NBP-Mean
Central Display Technical Alarms	Yes	Yes	
NBP (SYS, Mean, DIA)	Yes	Yes	
NBP Method	Oscillometric	Oscillometric	
NBP HR Range	30 to 240 bpm	40 to 240 bpm	
Systolic Range	30 to 250mmHg, increments of 1mmHg	30 to 250mmHg, increments of 1mmHg	
Systolic Accuracy	±5mmHg s < 8mmHg (relative to Biotek Simulator)	Not published	

Technology / Features Comparison	Nightingale Monitoring System	Siemens SC6000 Patient Monitor with SC3000 Multiview	Explanation of Differences: Nightingale as Compared to Predicate
Mean Range	20 to 230mmHg, increments of 1mmHg	20 to 230mmHg, increments of 1mmHg	
Mean Accuracy	±5mmHg s < 8mmHg (relative to Biotek Simulator)	Not published	
Diastolic Range	10 to 210mmHG, increments of 1mmHg	10 to 210mmHG, increments of 1mmHg	
Diastolic Accuracy	±5mmHg s < 8mmHg (relative to Biotek Simulator)	Not published	
SpO_2 (Percent SpO_2, Pulse Rate)	Yes	Yes	
SpO_2 Method	Absorption – spectrophotmetry	Absorption – spectrophotmetry	
SpO_2 Range	1 to 100%, 1% increments	0 to 100%	
SpO_2 Accuracy	70 to 100%: within ±2%; < 70%: unspecified	70 to 100% within ± 2%; < 70%: unspecified	
Pulse Rate Range	30 – 240 bpm	30 – 300 bpm	Nightingale gives better artifact rejection and pulse rate accuracy than the predicate with a lower maximum PR value.
Pulse Rate Accuracy	±1 bpm or ±5%, whichever is greater	±10%	
Respiration Sensing Leads	II	II	
Respiration Method	Impedance Pneumography	Impedance Pneumography	

Technology / Features Comparison	Nightingale Monitoring System	Siemens SC6000 Patient Monitor with SC3000 Multiview	Explanation of Differences: Nightingale as Compared to Predicate
Respiration Range	2 to 120 bpm	2 to 155 bpm	The predicate device is intended for use in Adult, Pediatric, and Neonatal populations. The Nightingale is intended for use in Adult populations only. Adult respiration maxima are lower than those for Pediatric and Neonatal populations, therefore the Nightingale's Respiration maximum is lower than the predicate's. A survey of other monitors shows an adult respiration maximum of 120 breaths per minute. Nightingale's maximum rate of 120 bpm allows better motion artifact rejection without adversely affecting adult respiration determinations.
Respiration Accuracy	± 1 bpm or ±2% whichever is greater	± 3 bpm	
Temperature	Yes	Yes	
Temperature Range	32° F to 122° F	32° F to 122° F	

Technology / Features Comparison	Nightingale Monitoring System	Siemens SC6000 Patient Monitor with SC3000 Multiview	Explanation of Differences: Nightingale as Compared to Predicate
Temperature Accuracy	± 0.1° F	± 0.2° F from 32°F to 86°F; ± 0.1° F from 86° F to 122° F	Nightingale is equivalent or better
Pacer Detection	Yes	Yes	

7 Assessment of Performance Data

7.1 Parameter Verification Method

The table below maps the new device's parameter to its verification method:

Parameter / Method	Heart Rate	Resp-iration Rate	SpO_2	Pulse Rate	Temp-erature	Systolic Press	Mean Press	Dia-stolic Press
Test against Standard	EC13							
Clinical Testing						•		•
Comparison Testing with respect to Predicate Device		•	•	•		•	•	•
Bench Tests	•				•	•	•	•

Table 2: PPM Parameter vs. Verification Method

7.2 Data Assessment

Using the verification methods described in the Parameter Verification Section (above), all Nightingale Monitoring System parameters test successfully.

8 FDA Guidances

Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm); FDA Center for Devices and Radiological Health (CDRH), Version 1.0, 11/05/1998.

NIBP Monitor Guidance; FDA Center for Devices and Radiological Health (CDRH), 03/10/1997.

Guidance for FDA Reviewers and Industry: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; FDA Center for Devices and Radiological Health (CDRH), 05/29/1998.

Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices; FDA Center for Devices and Radiological Health (CDRH), 09/09/1999.

9 Conclusion

The ZOE Nightingale Patient Monitoring System is a safe and effective device when used in accordance with Indications for Use and Intended Use.

The ZOE Nightingale Patient Monitoring System is substantially equivalent to the Siemens SC6000 Monitor and the Siemens SC3000 Multiview Central Display.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 12 2001

Mr. Paul M Fitzmeyer
Zoe Medical Inc.
460 Boston Street
Topsfield, MA 01983

Re: K001775
Trade Name: Zoe Medical Nightingale Monitoring System
Regulatory Class: II (two)
Product Code: 74 DRT
Dated: October 13, 2000
Received: October 17, 2000

Dear Mr. Fitzmeyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Stephen Rhodes

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

The device is indicated for use in adult patient populations in an environment where patient care is provided by healthcare professionals (e.g. Physician, Nurse, Technician) when:

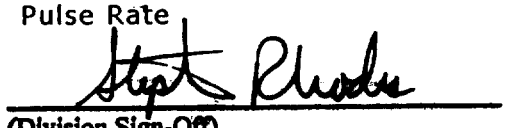
1. The professional determines that a device is required to measure any or all of the following patient parameters:

   - o Heart Rate
   - o Respiration Rate
   - o Temperature
   - o Systolic, Mean, and Diastolic Blood Pressure
   - o Functional Oxygen Saturation of Arterial Hemoglobin (SpO_2)
   - o Pulse Rate

And,

2. The professional determines that a device is required to issue visible and audible alarms when any or all of the following parameters exceed preset limits:

   - o Heart Rate
   - o Respiration Rate
   - o Temperature
   - o Systolic Blood Pressure
   - o Mean Blood Pressure
   - o Diastolic Blood Pressure
   - o Oxygen Saturation Percent
   - o Pulse Rate



(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001775